REMARKS/ARGUMENTS

Reexamination and reconsideration of this Application, withdrawal of the rejection, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the above amendments and remarks that follow.

Claims 43-60 and 62-68 are pending in the application. Claims 61 and 69-71 have been cancelled without prejudice or disclaimer in order to expedite prosecution. Applicants reserve the right to pursue the subject matter of the cancelled claims in related applications. Entry of this amendment is respectfully requested. It is believed that this amendment places the application in condition for allowability or, alternatively, places the claims in better form for appeal.

I. Restriction/Election

Applicants acknowledge the Examiner's decision to withdraw Claims 69-71 as being directed to a non-elected invention. In order to expedite prosecution, Applicants have cancelled Claims 69-71, but reserve the right to pursue those claims in a continuing application.

II. Section 103 Claim Rejections

Claim 61 stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,619,655 to Hanker *et al.* combined with GB 999,487 and U.S. Patent No. 5,385,887 to Yim *et al.* In order to expedite prosecution, Applicants have cancelled Claim 61. Accordingly, this rejection is moot and Applicants respectfully request withdrawal thereof.

Claims 43-60 and 62-68 stand rejected under 35 U.S.C. §103(a) as being unpatenable over U.S. Patent No. 5,356,629 to Sander *et al.* in combination with U.S. Patent No. 4,619,655 to Hanker *et al.* The Examiner relies upon the Sander reference as teaching a composition for effecting bone repair comprising biocompatible particles dispersed in a matrix. The Examiner acknowledges that the Sander reference does not list calcium sulfate hemihydrate as a possible bioresorbable material. Instead, the Examiner relies upon the Hanker reference as disclosing the use of calcium sulfate hemihydrate as a resorbable bone implant material and concludes that it would have been obvious to one of ordinary skill in the art to select calcium sulfate hemihydrate as the bioresorbable particles to be used in the Sander composition. In further support of this

rejection, the Examiner states that Sander provides a "non-limiting list" of bioresorbable particles and "provides no proscription against its use." Applicants respectfully traverse this rejection.

Applicants respectfully submit that there is clearly no motivation to combine the two cited references in the manner contemplated by the Examiner. The Sander reference is directed to a composition for effecting bone repair that possesses "improved moldability, workability and other handling characteristics upon being wetted with appropriate liquid medium" (column 1, lines 61-64). The Sander reference also stresses that the composition described therein will provide "improved resorption" upon implantation into a bone defect site (column 1, lines 65-68). The composition described in Sander comprises a matrix that is a highly viscous substance, but which is flowable to some extent (column 2, lines 35). Within the matrix, biocompatible particles are dispersed, which can be either bioabsorbable or nonbioabsorbable. The Sander reference discloses that the biocompatible particles should be present, after being wetted, at a concentration of about 35% to about 75% by weight.

The Sander patent expressly considers the use of plaster of paris (calcium sulfate hemihydrate) in bone repair compositions and carefully and unambiguously distinguishes the use of such compositions from the composition proposed in the Sander patent. It is clear that one of ordinary skill in the art would view the teachings of Sander as excluding the possibility of combining plaster of paris with the composition described in Sander, which is precisely the combination that the Examiner is suggesting. In the background section, the Sander reference teaches that plaster of paris has been used as a bioresorbable scaffold for implant and bone repair, but notes that plaster of paris suffers from several disadvantages. In particular, the Sander reference notes that plaster of paris will tend to lose its workability and set hard within 5 to 10 minutes after mixing with water, which makes it difficult to mold over an extended period of time. Further, the Sander reference stresses that plaster of paris can take over a month to be resorbed after implantation (column 1, lines 18-41). Quite contrary to its description of plaster of paris, the Sander reference expressly requires that the compositions described therein "will not set to a rock hard material like plaster of paris which, when wetted, begins to set and lose workability within 5 to 10 minutes" (column 2, lines 14-17)(emphasis added). The Sander patent

goes further to state that the composition described therein will "always remain in moldable semisolid form as long it is not permitted to dry out" (column 6, lines 1-2).

The Hanker reference is directed to precisely the type of plaster of paris compositions that the Sander reference makes a Herculean effort to distinguish. Hanker describes the use of plaster of paris as a carrier for a non-bioresorbable calcium material.

More convincing evidence that one of ordinary skill in the art would have no motivation to combine plaster of paris with the Sander composition could hardly be imagined. The Examiner has not explained how one of ordinary skill in the art would expect the Sander composition to function as it is intended, which means remaining in moldable semisolid form indefinitely, if plaster of paris is added. Neither the Hanker nor the Sander patent suggests that the addition of plaster of paris would do anything but negate the advantageous characteristics that Sander describes. In defense of this combination, the Examiner notes that Hanker teaches that the resorbability of calcium sulfate hemihydrate can be adjusted by adjusting its density. However, such a teaching fails to provide any motivation to add plaster of paris to the composition of Sander. If anything, such a teaching simply suggests that the plaster of paris composition of Hanker can be used without modification if resorbability of calcium sulfate hemihydrate is the only perceived problem.

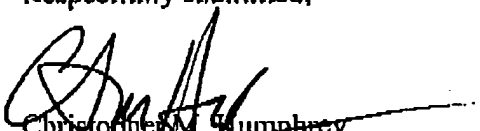
The Examiner goes further to state that Sander "motivates the addition of a matrix such as claimed to a calcium sulfate hemihydrate bone graft composition to improve the workability." Here, the Examiner appears to be turning the rejection on its head and using Hanker as the primary reference. Regardless, this statement is completely indefensible. There is nothing in Sander to motivate the addition of the matrix of the Sander composition to a calcium sulfate hemihydrate composition. Neither reference has anything to say whatsoever about what would occur when the matrix of Sander is combined with calcium sulfate hemihydrate. Such a composition is clearly not envisioned by either reference. In fact, as indicated above, the Sander reference suggests that plaster of paris should not be used at all in the Sander composition because (1) plaster of paris will tend to lose its workability very quickly; and (2) plaster of paris can take a very long time to be resorbed. There is certainly no teaching in Sander that the matrix described therein would somehow mitigate the workability problem associated with plaster of

paris. Rather, the matrix material of Sander is clearly offered as a substitute for plaster of paris as a carrier for a bone implant.

In summary, since the Sander reference so clearly differentiates a plaster of paris composition from the composition described therein, it is impossible to credibly assert that one of ordinary skill in the art would have been motivated to add calcium sulfate hemihydrate to the Sander formulation. There is nothing in either cited reference to suggest that such a composition would be advantageous in any way. Instead, the clear weight of the Sander reference suggests that such a combination would be unworkable and, in particular, suggests that such a combination would fail to meet the moldability and workability standard required by the Sander reference. In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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